UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,408	11/08/2001	Nobutaka Wakamiya	19036/34546A	6355

4743 7590 09/17/2003

MARSHALL, GERSTEIN & BORUN LLP
6300 SEARS TOWER
233 S. WACKER DRIVE
CHICAGO, IL 60606

EXAMINER
LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
1647	5

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,408	WAKAMIYA, NOBUTAKA	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/029,156* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. The Preliminary Amendment filed 3/19/02 has been entered into the record.

B. The Information Disclosure Statement, filed 2/25/02, has been entered into the record.

C. Claims 1-8 were pending in the application. However, these claims were cancelled in the Amendment filed 3/19/02 and new claims 9 and 10 were added. Therefore, claims 9 and 10 are pending and are the subject of this Office Action.

2. Note

A. Preliminary Amendment A, filed along with the Application (11/8/01) has not been entered into the record. However, this will be corrected upon mailing of this Office Action.

3. Specification

A. The specification is objected to since Applicants recite in the first line of the specification that PCT/JP95/02035 is now US Patent No. 6,110,708. However, a PCT cannot issue as a US Patent.

B. The title is objected to since it recites recombinant conglutinins and methods of producing these proteins. First, the claims are directed to MBPs, which are distinct from conglutinins (page 1, lines 16-18 of the specification). Second, the claims are not drawn to methods of producing these proteins, but are only drawn to the proteins themselves, though these claims include a method of *identifying* these proteins.

4. Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to Applicants claiming all MBPs which have either budding inhibition or anti-influenza A activity. Applicants have not provided any guidance or working examples of any MBP which has budding inhibition. If Applicants have demonstrated that MBPs can inhibit viral budding, it is required that Applicants point out exactly where in the specification there is support for this limitation. It appears that Applicants have only demonstrated that a small set of MBPs can have an activity on Influenza A activity. No demonstration of budding inhibition can be found in either the Figures or the Examples. Furthermore, even if Applicants demonstrate MBPs can inhibit budding, Applicants are not enabled for the scope of MBPs claimed, nor are they enabled for the scope of MBPs which can affect budding of any and all viruses. Applicants have claimed any and all MBPs which can inhibit viral budding by using a method which is part of the product claim. However, Applicants have only demonstrated (Tables 5, 6 and Figure 13) that a small set of MBPs inhibit growth and activity of the Influenza A virus and not the activity of all viruses covered by the scope of the claims. Most of the Examples provided in the specification demonstrate the effects of conglutinin, not MBPs.

To summarize, it appears that Applicants have only provided guidance and working examples of the effect of the MBPs in Table 5 and 6 and Figure 13 on specific activities (which does not include budding inhibition) of the Influenza A virus (and not all viruses encompassed by the scope of the claims). Furthermore, it is not known which MBP is being used in Figure 13. Therefore, the breadth of the claims is excessive and, due to the thousands of known viruses which are known to affect cells, it is not predictable to one of ordinary skill in the art which viruses the limited number of MBPs would affect. For these reasons, the Examiner has concluded that undue experimentation would be required to practice the invention as claimed.

5. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. The claims recite all MBPs which can inhibit the budding of any and all viruses or any and all activities of Influenza A. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "MBPs which can inhibit the budding of any and all viruses or any and all activities of Influenza A," alone is insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

6. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of "an N-terminal region containing a cysteine, a collagen-like region, a neck region and an carbohydrate recognition domain" are not known. It is not clear what a "collagen-like region" nor a "neck region" represent.

B. Claim 10 is also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble claims a purified mannan-binding protein. However, the remainer of the claim recites "calcium-dependent lectin."

7. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Wakamiya et al (reference C25 on the IDS submitted 2/25/02). The claims recite a MBP having budding or anti-Influenza A activity. Wakamiya teach a MBP having anti-Influenza A activity. This protein would inherently have the ability of inhibiting viral budding (Ex parte Novitski, 26 USPQ 1391). The methods of obtaining this protein is irrelevant and only the preamble is given patentable weight. Therefore, Wakamiya meet these limitations.

B. Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartley et al (reference C3 on the IDS submitted 2/25/02). The claims recite a MBP having budding or anti-Influenza A activity. Hartley teach a purified MBP having anti-Influenza A activity (Abstract and page 4359 under "Isolation of mannan-binding fraction of bovine serum). This protein would inherently have the ability of inhibiting viral budding (Ex parte Novitski, 26 USPQ 1391). The methods of obtaining this protein is irrelevant and only the preamble is given patentable weight. Therefore, Wakamiya meet these limitations.

8. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
September 15, 2003